Apothecary Products, Inc.®

JUL 14 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 (c)

The assigned 510(k) number is: K111856

Applicant:	Apothecary Products, Inc. 11750 12th Avenue South Burnsville, MN 55337
Contact person:	James Jenkins Sr. Regulatory Affairs Specialist Phone: 952.808.8364 Fax: 952.890.0418
Date prepared:	March 11, 2011
Name of Device:	Contact Lens Case, Model: Soft Grip Contact Lens Case; 68013, 68012 Model: Econo-Mate Contact Lens Case: K1010 Model: Deluxe Contact Lens Case; K1020
Device Classification Name:	Soft (hydrophilic) contact lens care products
Common or usual name:	Contact Lens Case
Classification:	Class II, 21 CFR 886.5928
Product Code:	LRX
Predicate Device information:	K093377; K991206; K042578
Device Description:	The API Soft Grip Contact Lens Cases and Deluxe Contact Lens Cases are designed for storage of contact lenses with adjoining dual wells that have screw top caps. The cases are labeled with an 'R' or 'L' to distinguish right and left lenses. The Econo-Mate Contact Lens Cases have two adjoining wells with integral hinged, self-sealing caps in which respective contact lenses are immersed. The cases are also labeled with an 'R' or 'L' to distinguish right and left lenses. The cases are available in a variety colors. The applicant devices are not sterile and not for heat-disinfection.

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Intended Use: The API Soft Grip, 68012, 68013; Deluxe, K1020; and Econo-Mate, K1010 Contact Lens Cases are intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Do not use during heat disinfection.

Comparison to Predicate Devices:

The API devices have the same intended use, similar design and materials as the predicate devices and are substantially equivalent with regards to safety and effectiveness.

Discussion of Non-Clinical Tests Performed in Determination of Substantial Equivalence:

Biocompatibility testing performed by third party laboratories demonstrated the materials are safe for use in contact lens storage and disinfection.

The applicant contact lens cases were subjected to an 8 hour leak test to ensure devices are effective against leaking. All Soft Grip, Deluxe, and Econo-Mate contact lens cases meet leak test criteria per test plan and have demonstrated to be effective against leaking.

Attribute	API Contact Lens Case Applicant Device; Soft Grip Model 68012 & 68013	Reliance Design & Mfg Corp, Polaris Contact Lens Case, Model #201 (K093377)
Classification Name	Contact Lens Case	Contact Lens Case
Intended Use	The API Soft Grip, 68012, 68013; Contact Lens Cases are intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Do not use during heat disinfection.	Polaris Contact Lens Case is for the storage of soft (hydrophilic), rigid gas permeable or hard contact lenses. It is to be used with chemical disinfectants only. It is not to be used in heat disinfection.
Disinfection Type	Chemical (Not Heat)	Chemical (Not Heat)
Design	Two adjoining wells with screw top caps into which respective lenses are immersed.	Two adjoining wells screwed with screw top into which respective lenses are immersed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Apothecary Products, Inc.
c/o Mr. Bhavesh Sheth
Intertek Testing Services
2307 East Aurora Road
Unit B7
Twinsburg, OH 44087

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Re: K111856
Trade/Device Name: Soft Grip Contact Lens Case (Models 68012 and 68012); Deluxe Contact Lens Case (Model K1020), Econo-Mate Contact Lens Case (Model K1010)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: June 28, 2011
Received: June 29, 2011

Dear Mr. Sheth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K111856

Indications for Use

510(k) Number (if known): K111856

Device Name: Contact Lens Case

Indications for Use:

The API Soft Grip, 68012, 68013; Deluxe, K1020; and Econo-Mate, K1010 Contact Lens Cases are intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Do not use during heat disinfection.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Denise Hayek

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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